JUN 5 2002

K013654

PRECISION SYSTEMS INC

16 Tech Circle Natick MA USA Phone 1 508 655 7010 Fax 1 508 653 6999
E-mail: precisionsystems@msn.com

Summary of Safety and Effectiveness: July 2, 2001

Manufacturer:	Precision Systems TM, Inc. 16 Tech Circle Natick, MA. 01760 Attention: Bill Haden
Proprietary Name:	ANALETTE TM
Classification Name:	862.2500
Intended Use:	An in vitro diagnostic automated clinical chemistry analyzer for the analysis of analytes in solution.
Predicate Device:	Synermed IR® 200 manufactured by Precision Systems TM, Inc, for Synermed® and as found in Synermeds® 510(k) IR200 vs. the Hitachi® 705.
Performance:	Substantially equivalence was established in comparative studies. It was concluded from these results that this product is safe and effective.
Safe Medical Device Act 1990	Precision Systems TM will make any additional safety and effectiveness information for the ANALETTE TM Clinical Chemistry Analyzer available to interested persons upon request.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 5 2002

Mr. Bill Haden
VP Scientific and Regulatory Affairs
Precision Systems Inc.
16 Tech Circle
Natick, MA 01760

Re: k013654
Trade/Device Name: PRECISION SYSTEMS ANALETTE CHEMISTRY ANALYZER
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test
Regulatory Class: Class II;
Product Code: JJF, CDQ, CEK, CEO, CFJ, CFM, CGA, CGS, CGX, CHG, CHH, CIG,CIT, CIX, CJE, CJE, CJY, CKA, JFJ, JGJ, JGY, JMO, JQB, KHS,KNK, LBR
Dated: April 8, 2002
Received: April 8, 2002

Dear Mr. Haden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K013654

Device Name: PRECISION SYSTEMS ANALETTE CHEMISTRY ANALYZER

Indications For Use:

The Precision Systems ANALETTE Chemistry Analyzer is intended for the quantitative determination of analytes in solutions, such as serum, plasma, or urine. It is an "open" system, which can use a variety of commercially manufactured reagents, such as, but not limited to Synermed's Reagents for Albumin, ALT, AST, ALP, Amylase, Calcium, CO2, Cholesterol, Creatinine, CK, Glucose, GGT, LDH, Magnesium, Phosphorus, Total Protein, Triglycerides, Urea Nitrogen, Total Bilirubin, Direct Bilirubin, HDL Cholesterol, UBIC, Iron, Chloride, and Uric Acid as shown in 510(k) K971491 using the ANALETTE under Synermed's name IR 200

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013654

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)